NOV 7 2002

K022655

Side Firing Needle with Vent Sheath

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information:

Trimedyne, Inc.
15091 Bake Parkway
Irvine, CA 92618
949-559-5300

Contact Person: Glenn Yeik
Executive Vice President

Summary Date: August 8, 2002

II. Device Name

Proprietary: To be determined

Common: Laser Fiber

Classification: Accessory to Laser-Powered Instrument

III. Predicate Device

The predicate devices for the Side Firing Needle with Vent Sheath are:

- Trimedyne Side Firing Switchable Tip with Suction/Irrigation cleared under K992230;
- SLT Diffuser™ Fiber cleared under K010041; and
- Índigo Diffuser-Tip™ Fiberoptic cleared under K990851.

IV. Device Description

The Side Firing Needle with Vent Sheath is a single use, disposable fiberoptic energy delivery device for use with the Omni™ Multiuse Handpiece and Fiber Assembly. The device consists of a near-contact laser fiber enclosed in a stainless steel pointed needle assembly. The device includes a luer connector assembly that connects the irrigation channel to an irrigation fluid source via an external line, as well as a vent sheath with proximal exhaust ports that terminates just proximal to the beam exit point. The Side Firing Needle with Vent Sheath is attached to the Omni Multiuse Handpiece through a quick-connect mechanism.

V. Intended Use

The Side Firing Needle with Vent Sheath is intended for superficial or interstitial incision, excision, resection, ablation, vaporization, coagulation and hemostasis and may be used with any cleared Holmium laser that has a compatible connector.

VI. Technological Characteristics

The Side Firing Needle with Vent Sheath differs from the Side Firing Switchable Tip with Suction/Irrigation in the addition of a pointed tip, a silver reflector to minimize energy emission in other than the main beam direction, and a vent sheath to provide an exhaust path for fluid and vapor.

VII. Nonclinical Data

The Side Firing Needle with Vent Sheath was subjected to a series of verification and validation tests, including performance and tissue affect studies.

VIII. Clinical Data

No clinical tests were submitted in this Premarket Notification.

IX. Conclusions Drawn From Testing

The Side Firing Needle with Vent Sheath is biocompatible, performs as intended, and has acceptable mechanical properties when used in accordance with its labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Trimedyne, Inc.
Glenn D. Yeik
Executive Vice President
15091 Bake Parkway
Irvine, California 92618

Re: K022655
Trade/Device Name: Trimedyne Side Firing Needle with Vent Sheath
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 8, 2002
Received: August 9, 2002

Dear Mr. Yeik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications Page

510(k) Number: K022655

Device Name: Trimedyne Side Firing Needle with Vent Sheath

Indications for Use: Superficial and interstitial incision, excision, ablation, vaporization, and coagulation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022655

Prescription Use ✓ OR Over-the-Counter Use _____